



AUG - 5 1998

Rec'd 8/7/98
jb

Mr. Siddharth S. Shastri
Director of Product Development
Jarrow Formulas, Inc.
1824 South Robertson Boulevard
Los Angeles, California 90035-4317

Dear Mr. Shastri:

This is in response to your letter of July 7, 1998 to the Food and Drug Administration (FDA) pursuant to 21 U.S.C. 343(r)(6) (section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the Act)). Your submission states that Jarrow Formulas, Inc. is making the following claims, among others, for the product "Cran Clearance:"

L-Glutamine 1000

"increased demand for glutamine during stress associated with exercise, illness or trauma"

Joint Builder

"People with osteoarthritis are often deficient in vitamin D3"

21 U.S.C. 343(r)(6) makes clear that a statement included in labeling under the authority of that section may not claim to diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases. The statements that you are making for these products suggest that they are intended to treat, prevent, or mitigate diseases, namely, general illness and trauma and osteoarthritis. The claims made for these products do not meet the requirements of 21 U.S.C. 343(r)(6). These claims suggest that these products are intended for use as drugs within the meaning of 21 U.S.C. 321(g)(1)(B), and that they are subject to regulation under the drug provisions of the Act. If you intend to make claims of this nature, you should contact FDA's Center for Drug Evaluation and Research (CDER), Office of Compliance, HFD-310, 7520 Standish Place, Rockville, Maryland 20855.

975-0163

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Please contact us if we may be of further assistance.

Sincerely,

James T. Tanner, Ph.D.
Acting Director
Division of Programs and Enforcement Policy
Office of Special Nutritionals
Center for Food Safety
and Applied Nutrition

Copies:

FDA, Center for Drug Evaluation and Research, Office of Compliance, HFD-300
FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of
Enforcement, HFC-200
FDA, Los Angeles District Office, Office of Compliance, HFR-PA240

cc:

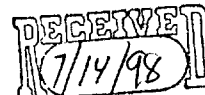
HFA-224 (w/incoming)
HFA-305 (docket 97S-0163)
HFS-22 (CCO, JGordon)
HFS-456 (File, r/f)
HFS-450 (file, r/f)
HFD-310 (BWilliams)
HFD-314 (Aronson)
HFS-600 (Reynolds)
HFS-605 (Bowers)
GCF-1 (Nickerson, Dorsey)
r/d:HFS-456:RMoore:8/3/98
Init:GCF-1:DDorsey:8/3/98
f/t:HFS-456:rjm:8/4/98:docname:60147b.adv:disc31

1824 South Robertson Blvd.
Los Angeles, CA 90035-4317
310/204-6936 • 800/726-0886

Fax Numbers
Orders 800/890-8955
General 310/204-2520
Administrative 310/204-5132

July 7, 1998

Dr. Elizabeth Yetley, Ph.D.
F.D.A.
Office of Special Nutrition
200 "C" St., S.W.
Washington, DC 20204



Please be advised that Jarrow Formulas, Inc. is marketing a product containing a "Structure and Function" statement on the label. According to the notification requirements set forth by the DSHEA (Dietary Supplement Health and Education Act, 1994) legislation, please be advised of the following:

Name of Product: Joint Builder, 120 Quik-SolvTM Tablets

Active Ingredient(s): Glucosamine Sulfate, MSM (Methylsulfonylmethane), Manganese (as Gluconate), Vitamin C (Calcium Ascorbate), Vitamin D3 (Cholecalciferol).

Claim(s): "Glucosamine Sulfate Formulation for Support of Cartilage and Joint Function."

Glucosamine Sulfate is stabilized using potassium chloride (KCl). In the body, glucosamine is an amino sugar synthesized from an amino acid (glutamine) and a carbohydrate (glucose). Glucosamines are subunits of glycosaminoglycans (GAGs) such as those found in synovial fluid, which lubricates joints. MSM is a sulfur donor which is essential to the formation of the chondroitin sulfates. Vitamin C and manganese are required for synthesis of collagen and cartilage. People with osteoarthritis are often deficient in Vitamin D3.

The following disclaimer appears on the label: These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure or prevent any disease.

These claims are limited to, and a result of, what we believe to be a substantial body of scientific evidence supporting the functional role of these nutrients. A compendium of relative published research substantiating the above statement(s) is on file at the corporate office.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Siddharth S. Shastri".

Siddharth S. Shastri, B.A., C.C.N.

Director of Product Development

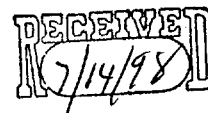
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July 7, 1998

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Please be advised that Jarrow Formulas, Inc. is marketing a product containing a "Structure and Function" statement on the label. According to the notification requirements set forth by the DSHEA (Dietary Supplement Health and Education Act, 1994) legislation, please be advised of the following:

Name of Product: L-Glutamine 1000, 100 Quik-Solv™ Tablets

Active Ingredient(s): L-Glutamine

Claim(s): "Supports Protein Synthesis." Glutamine is the most abundant amino acid in the body and is involved in many metabolic processes. Skeletal muscles are the primary sites of glutamine concentration. There is an increased demand for glutamine during stress associated with exercise, illness or trauma. Glutamine supplementation supports protein synthesis as well as the rate of glycogen production (by serving as a carbon donor). Glutamine also serves as a fuel source for intestinal mucosal cells and nucleotide synthesis by lymphocytes.

The following disclaimer appears on the label: These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure or prevent any disease.

These claims are limited to, and a result of, what we believe to be a substantial body of scientific evidence supporting the functional role of these nutrients. A compendium of relative published research substantiating the above statement(s) is on file at the corporate office.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Siddharth S. Shastri".

Siddharth S. Shastri, B.A., C.C.N.
Director of Product Development

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USAGE: As a dietary supplement, take 2 to 4 tablets daily, or as directed by your qualified health consultant.

Glucosamine Sulfate is stabilized using potassium chloride (KCl). In the body, glucosamine is an amino sugar synthesized from an amino acid (glutamine) and a carbohydrate (glucose). Glucosamines are subunits of glycosaminoglycans (GAGs) such as those found in synovial fluid, which lubricates joints. **MSM** is a sulfur donor which is essential to the formation of the chondroitin sulfates. **Vitamin C** and **manganese** are required for synthesis of collagen and cartilage. People with osteoarthritis are often deficient in **Vitamin D3**.

Joint Builder™, sodium free formula, may be taken with **Jarrow Formulas' BioSil**, the only biologically active form of silicon. Silicon enhances collagen and cartilage integrity.

These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure or prevent any disease.

Jarrow FORMULAS™

Joint Builder™

Glucosamine Sulfate
Formulation for
Support of Cartilage
and Joint Function

Dietary Supplement
120 Quik-Solv™ Tablets

Supplement Facts

Serving Size 2 Tablets

	Amount Per Two Tablets	% Daily Value
Glucosamine Sulfate (from 2000 mg 2GS•2KCl)	1,500 mg	*
MSM (Methylsulfonylmethane)	500 mg	*
Manganese (as Gluconate)	1 mg	50%
Vitamin C (Calcium Ascorbate)	100 mg	167%
Vitamin D3 (Cholecalciferol)	100 IU	25%

Percent Daily Value based on a 2,000 calorie diet.
* Daily Value not established

Other Ingredients: Calcium phosphate, cellulose, stearic acid, magnesium stearate, modified cellulose gum, silica. Quik-Solv™ tablets disintegrate within several minutes after ingestion.

Superior Nutrition and Formulation™ by
Jarrow FORMULAS, INC™
Los Angeles, CA 90035-4317

PROD # 19007



Lot #: Best Used Before:

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SUGGESTED USAGE: As a dietary supplement, take 1 to 4 tablets up to twice daily, or as directed by your qualified health consultant.

GLUTAMINE is the most abundant amino acid in the body and is involved in many metabolic processes. Skeletal muscles are the primary sites of glutamine concentration. There is an increased demand for glutamine during stress associated with exercise, illness or trauma. **Glutamine** supplementation supports protein synthesis as well as the rate of glycogen production (by serving as a carbon donor). **Glutamine** also serves as a fuel source for intestinal mucosal cells and nucleotide synthesis by lymphocytes.

These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease.

Lot #: Best Used Before:

Jarrow FORMULAS™

L-GLUTAMINE 1000

Pharmaceutical Grade
Suitable for Vegetarians

Supports Protein Synthesis

100 Quik-Solv™ Tablets 1,000 mg each

Each L-Glutamine 1000 tablet contains
L-GLUTAMINE 1,000 mg
Pure, Pharmaceutical Grade
Suitable for Vegetarians

Contains **NO** soy, wheat, yeast, dairy, artificial flavor, color, preservative, or other common allergen. Excipients: Cellulose (filler) and magnesium stearate (lubricant)

Superior Nutrition and Formulation™ by
Jarrow FORMULAS, INC™
Los Angeles, CA 90035-4317



PROD # 15033

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